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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,687	05/09/2002	Finbarr Paul Mary O'Harte	8830-8	5098

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EXAMINER
RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/09/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/937,687	Applicant(s) O'HARTE ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3* is/are allowed.

6)☒ Claim(s) *1,4,6-8,10 and 11* is/are rejected.

7)☒ Claim(s) *2,5,9 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The Sequence Listing filed January 8, 2002 has been approved.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title as set forth in the corresponding published PCT application would be acceptable.

3. The disclosure is objected to because of the following informalities: The amino acid sequences set forth at page 5 of the specification should not be referred to as Figures. Further, SEQ ID NOS must be inserted after every amino acid sequence subject to the sequence disclosure rules. See 37 CFR 1.821(d). At page 5, line 21, "N-acetylated" is misspelled. At page 12, line 32, "thereby" is misspelled. At page 16, line 15, "acetonitrile" is misspelled. At page 19, line 4, "panels" is misspelled. At page 21, line 25, "significantly" is misspelled. At page 25, line 25, "peptidases" is misspelled. The specification should be carefully reviewed for other misspellings. Appropriate correction is required.

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "Use" is not a statutory class of invention.

Note that the preliminary amendment filed September 28, 2001 did not contain any explicit instruction to cancel claim 7.

5. Claims 4, 6, 7, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 4, line 2, "comprising" should be changed to "consisting of" and at claim 4, line 3, "and/or" should be changed to "and", so that standard

Markush terminology is used. Claim 6 is unclear because of its use of the word "including". It is not clear if the scope of the claim is to be limited to the particular modifications recited in the "including..." phrase, or if any modification is embraced within the scope of the claim. It is not clear what constitutes a "Use" as is set forth in claim 7. It is not clear if Applicants are claiming, e.g., a method of use or a product with an intended use limitation. To the extent that the former was intended, the claim is indefinite because it does not include any positive process steps. See MPEP 2173.05(q). There is no antecedent basis in the claims for the phrase "the peptide" at claim 10, line 3. Note that the claim uses the terminology "GIP of analogues thereof", not "peptide", in lines 1-2. For analogous reasons, there is no antecedent basis for the phrase "the peptide synthesis reaction" at claim 11, lines 10-11. Claim 10, lines 4-5, is unclear because it is not clear to what the tyrosine in the form of F-moc protected Tyr(tBu)-Wang resin is to be added. Because the claim later states (see lines 9-11) that the modified tyrosine is added to the peptide synthesis reaction, i.e. to the reaction medium in which the GIP or analogue thereof has been synthesized, presumably the tyrosine is added to something other than this at lines 4-5 of the claim. However, there is no previous mention in the claim of any other substance to which the tyrosine can be added. At claim 11, line 3, "comprising" should be changed to "consisting of" and "or" should be changed to "and" so that standard Markush terminology is used.

6. Claim 5 is objected to because of the following informalities: At claim 5, line 2, "acid" should be inserted after "4-amino butyric". Appropriate correction is required.

7. Claims 4-6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. To the extent that claims 4-6 depend upon claim 3, they do not further limit the subject matter of claim 3. Claim 3 is drawn to a specific peptide analogue, Tyr^1 glucitol GIP(1-42) modified at the side chain of at least one lysine residue by fatty acid addition. There is no indication that the claim permits any further substitution or modification of the analogue. Accordingly, claims 4-6, which would require further substitution or modification of the analogue, do not further limit claim 3. [If Applicants amend claim 3 in response to this objection to indicate that substitutions and/or modifications of the analogue are embraced by the independent claim, Applicants need to choose claim language which makes it clear as to whether substitution or modification of the Tyr^1 glucitol residue or of the fatty acid-modified lysine residues is permitted.]

8. Claim 7 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend upon another multiple dependent claim. See MPEP § 608.01(n). Note that claim 7 is dependent upon multiple dependent claims 4-6.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by the Fujii et al article (Chem. Pharm. Bull., Vol. 34, pages 2397-2410). The Fujii et al article teaches the chemical synthesis of human GIP. Prior to final deprotection of the 42-residue peptide, the tyrosine residue at position 1 is protected, i.e. modified, at N^{α} with Z(OMe) and the glutamic acid residue at position 3 is protected, i.e. modified, at its sidechain with OChp. The protected

42-residue peptide is isolated as a powder. See Figure 2 and page 2407, fourth and fifth paragraphs. With respect to instant claim 6, this rejection assumes that the scope of the claim is not limited to the particular modifications recited in the "including..." phrase. With respect to instant claim 8, an intended use limitation does not impart patentability to product claims which are otherwise anticipated by or obvious over the prior art.

11. Claim 3 is allowed. Claims 2, 9, and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 5 would be allowable if rewritten to overcome the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Claim 4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Claims 10 and 11 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

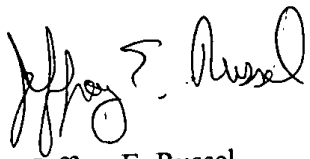
The prior art of record does not teach or suggest GIP analogues having the substitutions or modifications required by instant claims 2-5. With respect to instant claims 9 and 12, because the Fujii et al article does not teach the protected 42-residue peptide to have pharmaceutical activity, there is no motivation or suggestion to combine the protected 42-residue peptide with a pharmaceutically acceptable excipient or to administer it in vivo. With respect to instant claims 10 and 11, the prior art of record does not teach or suggest forming a modified tyrosine residue from a protected tyrosine residue attached to a Wang resin and then detaching the modified

tyrosine residue from the Wang residue and attaching it as the N-terminus to form a GIP analogue.

The O'Harte et al article (Reference AC of the Information Disclosure Statement filed May 9, 2002) has been carefully considered but is not deemed to teach or suggest the instant claimed invention. The Tyr^1-glucitol GIP analogue of the article is excluded from the scope of Applicants' claims by the proviso in claim 1 and by the requirement for lysine modification with a fatty acid in claim 3.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

July 8, 2003